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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/344,735	06/25/1999	HERMAN BERG	GENE1110-1	9401
35938	7590	03/22/2004	EXAMINER	
BIOTECHNOLOGY LAW GROUP 658 MARSOLAN AVENUE SOLANA BEACH, CA 92075			WILLIAMS, CATHERINE SERKE	
			ART UNIT	PAPER NUMBER
			3763	25

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/344,735

Applicant(s)

BERG ET AL.

Examiner

Catherine S. Williams

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 13-18, 23, 24, 26-40, 42, 44, 45, 52-57, 62, 63 and 65-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 13-18, 23, 24, 26-28, 30-33, 35-39, 42, 44, 45, 52-57, 62, 63 and 65-67 is/are rejected.
- 7) ☒ Claim(s) 29, 34, 40 and 68 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 13-14, 17-18, 23-24, 26, 32-33, 36-39, 42, 44-45, 52-53, 56-57, 62-63 and 65 are rejected under 35 U.S.C. 102(e) as being anticipated by Walker et al (6,041,252). Walker discloses a drug delivery system that includes a method for drug delivery to a specific target in the human body combined with photodynamic therapy. The method teaches providing a photooxidizing agent, applying an electric pulse to electroporate a cell with the photooxidizing agent, and applying a light (laser) to the cell (after electroporation). See 3:16-21 and 38:26-36. Multiple electric pulses are applied (7:16) by a plurality of electrodes (8:3). See also 7:4+ for amplitude and duration. The wavelength of the light is 630nm (see 38:33). The reference also teaches a method of heating the cell. See 39:55+. The photooxidizing agent can be hematoporphyrin.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-28 and 66-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. Walker meets the claim limitations as described above but fails to include a cytostatic agent specifically daunomycin, adriamycin or actinomycin.

At the time of the invention, it would have been obvious to substitute any of the above cytostatic agents for the hematoporphyrin of Walker since they are equivalent in the art. Any of the above cytostatic agents would equally perform the same function, therefore the substitution would have been proper. Additionally, the motivation for the incorporation would have been in order to utilize a readily available agent in the method.

Claim 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. Walker meets the claim limitations as described above but fails to include a meander electrodes. At the time of the invention, it would have been obvious to substitute meander electrodes into the invention of Walker. The meander electrodes would equally perform the same function, therefore the substitution would have been proper. Additionally, the motivation for the incorporation would have been in order to utilize a readily available electrode in the method.

Claims 15-16, 31 and 54-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al in view of Kennedy et al (US Pat# 5,079,262). Walker meets the claim limitations as described above but fails to include using a tungsten lamp or protoporphyrin IX.

However, Kennedy discloses a method of photodynamic therapy that includes using a tungsten lamp and protoporphyrin IX. At the time of the invention, it would have been obvious to substitute the tungsten lamp of Kennedy for the laser and agent of Walker. Both methods are analogous in the art and therefore a combination is proper. Additionally, the tungsten lamp and protoporphyrin IX of Kennedy would perform the same function just as well as that disclosed by Walker. The motivation for the incorporation would have been in order to use a readily available agent and light source in the method.

#### ***Allowable Subject Matter***

Claims 29, 34, 40 and 68 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Response to Arguments***

Applicant's arguments filed 1/12/04 have been fully considered but they are not persuasive.

I. Applicant argues that the prior art (Walker) does not teach a pharmaceutically acceptable formulation consisting essentially of (i) a photosensitive agent or a plurality of different photosensitive agents. Specifically, applicant argues that since the formulation of the prior art contains liposomes, the prior art formulation cannot read on a formulation consisting essentially of a formulation that does not recite liposomes. However, "consisting essentially of"

occupies a middle ground between closed claims that are written in a 'consisting of' format and fully open claims that are drafted in a 'comprising' format." PPG

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*Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir.1998). See also *Atlas Powder v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); *In re Janakirama-Rao*, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); *Water Technologies Corp. vs. Calco, Ltd.*, 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to “comprising.” See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355 (“PPG could have defined the scope of the phrase consisting essentially of” for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention.”). See also *In re Janakirama-Rao*, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of “consisting essentially of,” applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant’s invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964).

M.P.E.P. § 2111.03 (8<sup>th</sup> edition).

Applicant has not shown how the introduction of liposomes would materially change the characteristics of applicant’s invention. Additionally, one can ascertain from applicant own disclosure that liposomes would not materially change the characteristics of the formulation since page 13 line 24 of the specification discloses that liposomes may be included in the composition.

The transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials or steps “and those that do not materially affect the basic and novel characteristic(s)” of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original) (Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid “consisting essentially of” certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants’ specification indicated the claimed composition can contain any well-known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.).

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M.P.E.P. § 2111.03 (8<sup>th</sup> edition).

Since applicant's specification discloses that the formulation may contain liposomes and the prior art teaches a formulation including a photosensitive agent, the prior art reads on the language of "consisting essentially of".

II. While the 103 rejections in the previous office action only list the dependant claims, the independent claims (from which these listed claims depend) are inherently included in the rejection and are therefore implicitly considered obvious in light of the prior art. Dependent claims cannot stand on their own and inherently include all of the limitations from the independent claim from which they depend, e.g. Claim 2. The system of claim 1 further comprising. Therefore, if a dependent claim is listed as being rejected then its independent claim must also be included in the same rejection regardless of whether it is listed.

III. The '252 reference and '262 are analogous in light of the fact that both references teach a method for treatment of cancer/tumor. The court has found "the similarities and differences in structure and function of the inventions determine the analogy of the references. These two reference not only teach methods for treating tumors but also include using photodynamic therapy as a method for treating tumors. See, for example, *Ex parte Bland*, 3 USPQ2d 1103 (Bd. Pat App. & Inter. 1986) (Claims were drawn to a particulate composition useful as a preservative for an animal foodstuff (or a method of inhibiting fungus growth in an animal foodstuff therewith) comprising

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verxite having absorbed thereon propionic acid. All references were concerned with absorbing biologically active materials on carriers, and therefore the teachings in each of the various references would have been pertinent to the problems in the other references and the invention at hand.) M.P.E.P. § 2141.01(a) (8<sup>th</sup> edition).

IV. While applicant asserts that neither of the reference provides a motivation for combining the respective disclosures ('252 and '262), the motivation does not have to be provided by the references themselves.

The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). See also In re Kotzab, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (setting forth test for implicit teachings); In re Eli Lilly & Co., 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) (discussion of reliance on legal precedent); In re Nilssen, 851 F.2d 1401, 1403, 7 USPQ2d 1500, 1502 (Fed. Cir. 1988) (references do not have to explicitly suggest combining teachings). M.P.E.P. § 2144 (8<sup>th</sup> edition).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after



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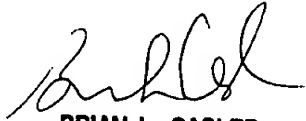
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine S. Williams *CSW*.  
November 25, 2003

  
**BRIAN L. CASLER**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 3700**